REMARKS

Any fees that may be due in connection with this response may be charged to Deposit Account 50-1213. If a Petition for Extension of time is needed, this paper is to be considered such Petition.

Claims 1, 3-9 and 11-30 are pending in this application. Applicants gratefully acknowledge the Examiner's indication that claims 1, 3-9, 11-17 and 22-28 are allowable. Claims 17, 18 and 30 are amended herein. The claims are amended in order to correct minor informalities. No new matter has been added nor are the amendments intended to alter the scope of the claims or to avoid any cited art.

New claims 31 and 32 are added herein. Claims 31 and 32 are directed to the methods of allowed claims 1 and 5, respectively, where the reader head further contains a second light emitting diode and a third fiberoptic conductor optically coupled to the second light emitting diode, where the plurality of fiberoptic conductor ends arranged in a sigmoidal distribution further includes a third portion of fiberoptic conductor ends of the third fiberoptic bundle. Support for new claims 31 and 32 is found in the specification, for example, at page 39, line 6, through page 40, line 21, and at Figures 17 through 19. No new matter is added by these new claims.

THE REJECTIONS OF CLAIMS 18 and 21 UNDER 35 U.S.C. §103

Relevant law

To establish a *prima facie* case of obviousness, prior art references when combined must teach or suggest all the claim limitations. "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

Another requirement to establish a *prima facie* case of obviousness is a teaching or suggestion to modify or combine the references to arrive at the claimed subject matter. "Under section 103, teachings of references can be combined *only* if there is some suggestion or incentive to do so." *In re Fritch*,

23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (emphasis original). "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification." *In re Fritch*, at 1783-84. Without the teachings of the prior art suggesting the combination, it is impermissible to pick and choose among isolated disclosures in the prior art to conclude that the claimed invention is obvious. *In re Fine*, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988).

THE REJECTION OF CLAIMS 18 AND 21 UNDER 35 U.S.C. §103(a)

Claims 18 and 21 are rejected under as being unpatentable over Connolly (International PCT application No. WO96/13707) in view of Augstein (U.S. Patent No. 5,665,310) because Connolly teaches an optical reading apparatus that contains a separate readhead, which does not move, and Augstein teaches an apparatus that contains a moving measuring head for analyzing a sample. The Examiner concludes that it would have been obvious to the ordinarily skilled artisan to have used the moving head of Augstein in the apparatus of Connolly. This rejection is respectfully traversed.

The claims

Claim 18 is directed to a method for reading a surface of a test strip having an image by moving a reader head in a reflectance reader to a first position over the surface, measuring a first amount of light reflected from the surface, uniformly illuminating the surface with light of a first wavelength, and measuring a second amount of light reflected from the surface, uniformly illuminating the surface with light of a second wavelength, and measuring a third amount of light reflected from the surface, repeating each of the measuring and illuminating steps at additional positions on the surface of the test strip until the image on the surface is scanned, and determining an intensity or shape of the image.

Claim 21 is directed to a method for reading a surface of a test strip having an image by moving a reader head in a reflectance reader to a first position over the surface, measuring a first amount of light reflected from the surface, uniformly illuminating the surface with light of a first wavelength, and measuring a second amount of light reflected from the surface, uniformly illuminating the surface with light of a second wavelength, and measuring a third amount of light reflected from the surface, and moving the reader head in a stepwise fashion to a plurality of positions over the test strip, where three light measurements are made at each of the plurality of positions to determine an intensity or shape of the image.

Connolly

Connolly teaches a diagnostic test strip for use in an analyzer for measuring analyte in a sample. The test strip includes an elongated body having first and second ends and a hinged portion between the ends so that the first end is foldable over the second end or the body. The first and second ends each have an opening aligned with each other when the first end is folded. A carrier layer means includes a separating layer for whole blood cells.

In methods that use the test strip, the density of a color reaction is determined using a spectrophotometric device that includes a hand-held housing, a test strip holding region that is located above three light detectors or sensors each disposed within a port. During test operation, a test strip is inserted into the holding region so that the test strip openings are located adjacent to the ports. Multiple wavelengths can be used to irradiate the strip in conjunction with multiple chromophores, or with different angles of emission when the light emitters are at different angles with the surface of the test strip.

Light sensors take a reading from the exposed portions of the strip. In operation, as a test strip is inserted into the device, the instrument detects a change in the exposed portion and identifies the test type by reading a color coded label. A sample is then applied and the measurement cycle commences.

A measurement cycle is carried out to ensure that the proper amount of sample was added to the test strip. A measurement cycle is carried out to measure the end of the reaction on the test strip. The instrument measures the density of the reaction and determines the concentration.

The method of Connolly does not entail moving a reader head over the surface of the test strip. Connolly also does not teach or suggest repeating the measuring and illuminating steps at a plurality of positions on the surface of the test strip nor determining an intensity or shape of an image, nor does Connolly teach or suggest uniformly illuminating the surface of a test strip.

Augstein

Augstein describes a measuring head for evaluating a test strip, where the measuring head rests on a spacer and thereby ensures a defined distance between the measuring head and the surface of the test strip. The test strip of Augstein has separate and different test fields separated by measuring openings, where the different test fields have different thicknesses, and the different test fields serve to evaluate different analytes. In examining various test fields, the measuring head moves relative to the test strip, where the measuring head is guided by the spacer to maintain a constant distance between the surface of each test field and the measuring head. Evaluation of each test field with different wavelengths can be carried out using several measuring heads, where each head uses one specific type of radiation.

Augstein does not teach or suggest a method that requires repeating the measuring and illuminating steps at a plurality of positions on the surface of the test strip and determining a parameter associated with the intensity or shape of the image, nor uniformly illuminating a test strip.

Analysis

It is respectfully submitted that a *prima facie* rejection of these claims has not been established because the combination of teachings of the cited references does not teach or suggest all the claim limitations to result in the

instantly claimed methods. Furthermore, the teachings of Connolly and Augstein would not have motivated one of ordinary skill in the art to arrive at the claimed methods.

a. The combination of teachings does not result in the methods of claims 18 and 21

The combination of the cited references do not teach or suggest all of the claim limitations because neither Connolly nor Augstein, singly or in combination, teaches or suggests taking measurements at a plurality of positions along the surface of test strip, nor uniformly illuminating the surface of a test strip as required by claims 18 and 21, nor determining the intensity or shape of an image.

1. The references do not teach measurements at a plurality of positions over a test strip

Claim 18 includes repeating the measuring and illuminating steps at additional positions on the surface of the test strip, and claim 21 includes moving the reader head in a stepwise fashion to a plurality of positions over the test strip and making light measurements at each position. Connolly does not teach or suggest measuring multiple positions of a test strip. Augstein describes a measuring head that can move over a test strip in measuring separate and different test fields separated by measuring openings, where the different test fields have different thicknesses, and the different test fields serve to evaluate different analytes. (Augstein, column 1, lines 61-67). Thus, the movement of the measuring head permits a measurement of the surface of each different test field of the test strip. (Augstein, column 4, lines 26-28). Augstein does not teach or suggest moving a reader head to multiple positions over the same test field and carrying out additional measurements of the same test field.

Accordingly, Connolly and Augstein, when combined, do not teach or suggest moving a reader head to multiple positions over a test strip and making light measurements at each position. Thus, the combination of Connolly and Augstein do not teach or suggest all limitations of claims 18 and 21.

Claim 21 further recites that the light measurements at a plurality of positions are made to determine an intensity or shape of the image. Connolly does not teach or suggest measuring light at a plurality of positions for any purpose. Augstein teaches making a measurement over each of multiple different surfaces, not the same surface. Thus, Augstein does not teach or suggest multiple light measurements made to determine an intensity or shape of an image. Accordingly, combining the teachings of Connolly and Augstein does not result in the use of light measurements from a plurality of positions to determine an intensity or shape of an image, as recited in claim 21.

2. The references do not teach uniformly illuminating the surface of a test strip

Claims 18 and 21 recite uniformly illuminating the surface of the test strip. Connolly teaches illumination of the test strip with different wavelengths positioned at different angles with respect to the test strip. (Connolly, page 21, line 30, through page 22, line 2), but does not teach or suggest uniform illumination. Augstein teaches the importance of the distance between the light-reflecting surface and the measuring head (Augstein, column 3, lines 11-16), but does not teach or suggest uniformly illuminating the surface.

The Office Action appears to suggest that Augstein's teaching of moving a reader head relative to the test surfaces represents a teaching of uniformly illuminating a test strip surface. Augstein teaches that a movable reader head is desirable to read multiple test elements, but Augstein is silent regarding the effect moving a reader head has on illuminating a test strip surface. Moreover, no other portion of Augstein teaches or suggests that the method of Augstein includes uniformly illuminating a test strip surface. Accordingly, neither Connolly nor Augstein teach or suggest the recited claim element of uniformly illuminating the test strip surface.

Because neither Connolly nor Augstein teaches or suggest measurements at a plurality of positions over a test strip nor uniformly illuminating the surface of the test strip, the references, when combined, cannot establish the methods

of claims 18 and 21 as *prima facie* obvious because the references do not teach or suggest all elements of the claims.

b. There would have been no motivation to do what applicant has done

The teachings of Connolly or Augstein, singly or in combination, would not have led one of ordinary skill in the art to move a reader head to a plurality of positions over the surface of a test strip to take additional measurements in the manner recited in the claimed methods.

Connolly teaches three measurement cycles: a first for ensuring that the proper amount of sample is applied to the test strip, a second for determining when the end of the chemistry reaction on the test strip has occurred, and a third for measuring the final density of the test strip. (Connolly, page 19, lines 5-16). If the reader head were moved to a plurality of positions over the surface and the set of three measurements taught by Connolly were carried out multiple times, such would require applying additional sample and further chemistry reaction for each set of three measurements, resulting in a change to the image on the surface of the test strip at each of the plurality of positions. Alternatively, if the unchanged image on the surface of the test strip were to be measured when the reader head moved to a plurality of positions over the surface, Connolly would teach, if anything, that only a single measurement should be made at each position. There is no suggestion by Connolly to carry out three measurements at each of a plurality of different positions for the purpose of measuring a particular image. If anything, the teachings of Connolly would motivate one of ordinary skill in the art to carry out only a single measurement after the end of the chemistry reaction on the test strip has occurred.

Augstein does not cure the deficiencies of Connolly because Augstein does not teach or suggest using a reader head to take more than one measurement at a particular position over a test strip.

Claim 18 recites three measurements of the surface of a test strip from a first position and repeating each measuring step at additional positions on the surface. Claim 21 recites three measurements of the surface of a test strip from a first position and three measurements at each of a plurality of positions of a test strip. The teachings of Connolly and Augstein provide no motivation to carry out three measurements of the surface of a test strip from a first position and three measurements of the surface of a test strip from additional or a plurality of positions. At best, the combined teachings suggest making single measurements from each of a plurality of positions. "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification." *In re Fritch*, at 1783-84. The cited references do not suggest the desirability of the modification of the claimed methods. Therefore, modification of the cited references to encompass the methods of claims 18 and 21 not obvious.

Further, there is no teaching or suggestion within Connolly or Augstein indicating the desirability of uniformly illuminating the test strip. Connolly teaches illumination at an angle with respect to the test strip. Augstein is silent with regard to the manner of illumination of the test strip. Therefore, neither Connolly nor Augstein teach or suggest desirability of illuminating the test strip uniformly.

THE REJECTION OF CLAIMS 19 AND 20 UNDER 35 U.S.C. §103(a)

Claims 19 and 20 are rejected as being unpatentable over Connolly in view of Augstein. In addition to the reasons set forth in the rejection of claims 18 and 21, the Office Action states that the cited references teach or suggest transmitting light at an angle normal to the test strip surface, and measuring light reflected normally from the surface. This rejection is respectfully traversed.

The Claims

Claim 19 is directed to a method for reading a surface of a test strip having an image, by moving a reader head in a reflectance reader to a first position over the surface having the image, measuring a first amount of light reflected from the surface comprising the image, transmitting light of a first wavelength onto the surface at an angle normal to the surface, and measuring a second amount of light reflected normally from the surface, and transmitting light of a second wavelength onto the surface at an angle normal to the surface, and measuring a third amount of light reflected normally from the surface.

Claim 20 is directed to a method for reading a surface of a test strip having an image, by, with a reader head in a reflectance reader at a first position over the surface having the image, measuring a first amount of light reflected from the first position of the surface, transmitting light of a first wavelength onto the first position of the surface at an angle normal to the surface, and measuring a second amount of light reflected normally from the surface, transmitting light of a second wavelength onto the first position of the surface at an angle normal to the surface, and measuring a third amount of light reflected normally from the surface, moving the reader head to a second position over the surface having the image, measuring a fourth amount of light reflected from the second position on the surface, transmitting light of the first wavelength onto the second position of the surface at an angle normal to the surface, and measuring a fifth amount of light reflected normally from the surface, transmitting light of the second wavelength onto the second position of the surface at an angle normal to the surface, and measuring a sixth amount of light reflected normally from the surface, and determining a parameter correlated with an intensity or shape of the image.

Analysis

A *prima facie* rejection of these claims has not been established because the combination of teachings of the cited references does not teach or suggest all the claim limitations to result in the instantly claimed methods. Moreover, the teachings of Connolly cannot be modified to arrive at the claimed methods because such a modification would be contrary to the teachings of Connolly. Claim 20 is also not obvious in view of the references because the references do not teach or suggest moving the reader head to a second position over the surface of the test strip, and carrying out three additional measurements at the second position.

1. The references do not teach or suggest transmitting light at a normal angle

Neither Connolly nor Augstein teaches or suggests transmitting light onto the surface at an angle normal (or perpendicular) to the surface, and measuring light reflected normally from the surface. Thus, the combination of Connolly and Augstein does not teach or suggest all elements of the claimed methods.

2. Connolly's teachings are contrary to transmitting light at a normal angle

Furthermore, one of ordinary skill in the art cannot follow the teachings of Connolly to arrive at the claimed methods. Connolly teaches the desirability of particular angles that are contrary to the angles of the claimed method, and modifying the angles taught by Connolly to arrive at the claimed methods would eliminate the benefit taught by Connolly of having the light sources at different angles.

Connolly teaches the desirability of using two light sources at different angles (one at 40 degrees and one at 50 degrees) for correcting problems positioning the test strip. Connolly teaches that a tilt in the test strip will result in positive and negative contributions to the reflection readings. (Connolly, page 21, line 28, to page 22, line 8). To achieve the claimed method, one of ordinary skill in the art must orient the light at an angle normal to the surface, not at 40

or 50 degrees relative to the surface, as taught be Connolly. Orienting the light at an angle normal to the surface, however, would eliminate the benefits taught by Connolly that result when the light sources are used at two different angles. Thus, to achieve the method of claims 19 or 20, one of ordinary skill in the art must proceed contrary to the teachings of Connolly.

The Office Action states, "Applicant further argues that a tilt in the test strip will result in positive, and negative contributions to the reflection readings are also not found persuasive." (Office Action, page 8, paragraph 11). Applicants respectfully submit that the statement regarding a tilt in the test strip is not Applicants' argument, but is instead the teachings of Connolly. For example, Connolly, at page 21, line 28, to page 22, line 2, states:

> If the detector is at "0" angle and the emitters of the same or different wavelengths are at different angels[sic] (one at 40° and one at 50°) the tilting of a surface will positively contribute to one reading while the other contributes in a negative manner thus cancelling the error presented by the angle presentation of the surface.

The above statement must be treated as the teachings of Connolly, not the arguments of Applicants. A reference must be considered in its entirety, i.e., as a <u>whole</u>, including portions that would lead away from the claimed subject matter. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983). Thus, the above teachings by Connolly cannot be ignored or deemed unpersuasive; those teachings must be considered as part of the entire teachings of Connolly. Accordingly, Connolly must be considered to teach that having the light source at non-perpendicular angles would have the desirable result of decreasing measurement error.

The totality of a reference must be considered, and proceeding contrary to accepted wisdom in the art is evidence of nonobviousness. *In re Hedges*, 783 F.2d 1038, 228 USPQ 685 (Fed. Cir. 1986). The fact that one of ordinary skill in the art must proceed contrary to the teachings of Connolly to achieve the methods of claims 19 or 20 is, therefore, evidence of the nonobviousness of

claims 19 and 20. Accordingly, Applicants respectfully request that the Examiner remove this ground for rejection of claims 19 and 20.

3. Claim 20 is also unobvious as it recites carrying out measurements at a second position over the test strip

Claim 20 is further unobvious over the cited references because the references do not teach or suggest moving the reader head to a second position over the surface of the test strip, and carrying out three additional measurements at the second position. As applicants discussed above regarding claims 18 and 19, neither Connolly nor Augstein teach or suggest carrying out three measurements at a second position over the test strips; and, moreover, the teachings of Connolly would not motivate one of ordinary skill in the art to modify either reference to arrive at the claimed methods. Thus, on the additional basis of these reasons, the references do not teach or suggest the method of claim 20.

THE REJECTION OF CLAIMS 29 AND 30 UNDER 35 U.S.C. §103(a)

Claims 29 and 30 are rejected under 35 U.S.C. §103 as being unpatentable over Connolly and Augstein, and in further view of Hernicz, U.S. Patent No. 4,659,229) because Connolly, when combined with Augstein, allegedly teaches reading a test strip at multiple wavelengths and a movable read head, and Hernicz allegedly teaches a read head with an aperture and use of fiberoptic bundles to illuminate a sample and measure reflected light. This rejection is respectfully traversed.

The Claims

Claims 29 and 30 are directed to methods for reading the surface of a test strip having an image by moving a reader head in a reflectance reader to a first position over the surface having the image, measuring a first amount of light reflected from the surface, uniformly illuminating the surface with light of a first wavelength, and measuring a second amount of light reflected from the surface, and uniformly illuminating the surface with light of a second wavelength, and measuring a third amount of light reflected from the surface.

The methods further include emitting the light of the first wavelength from a light emitting diode, transmitting the emitted light of the first wavelength through a first fiberoptic bundle to the surface of the test strip, and transmitting the second amount of light reflected from the surface of the test strip through a second fiberoptic bundle to a photodetector, where claim 30 also includes emitting the light of the second wavelength from a second light emitting diode, transmitting the emitted light of the second wavelength through a third fiberoptic bundle to the surface of the test strip, and transmitting the third amount of light reflected from the surface of the test strip through the second fiberoptic bundle to the photodetector.

Teachings of the cited references

The teachings of Connolly and Augstein are discussed above. Neither Connolly nor Augstein singly or in combination teaches or suggests a method using fiberoptic bundles.

Hernicz

Hernicz does not cure the deficiencies in the teachings of Connolly and Augstein. Hernicz teaches a reader head with reduced height sensitivity that measures reflectance from a sample. The reader head is configured such that the upper portion of the inner surface is hemispherically shaped and the lower portion is conically shaped. In the method of Hernicz, a sample is exposed to light from a high intensity flash lamp or continuous incandescent lamp, the light is reflected from the sample surface, and the reflected light is received by two fiber optic bundles (one sample and one reference) and transferred to a pair of detectors.

Hernicz does not teach or suggest moving a reader over the surface of a test strip nor uniformly illuminating the test strip. Hernicz does not teach or suggest transmitting light emitted from a light emitting diode through a fiberoptic bundle to the surface of a test strip. Moreover, Hernicz does not teach or suggest transmitting light emitted from any light source through a

fiberoptic bundle to the surface of a test strip nor through fiberoptic bundles arranged to achieve uniform illumination and maximize reflected light (by using, for example, a sigmoidal distribution). not recited in claims 29-30

Analysis

A *prima facie* rejection of these claims has not been established because the combination of teachings of the cited references does not teach or suggest all the claim limitations to result in the instantly claimed methods. Furthermore, the teachings of Hernicz cannot be modified to arrive at the claimed methods because such a modification would change the principle of operation of the teachings of Hernicz.

1. None of the references teach using a fiberoptic bundle to transmit light from a light source to a test strip surface

As discussed above, neither Connolly and Augstein, singly or in any combination thereof, teaches or suggests an aperture in a reader head or the use of fiberoptic bundles. Hernicz teaches use of fiberoptic bundles to receive reflected light, but does not teach or suggest use of a fiberoptic bundle to transmit light from a light source to the surface of a test strip.

The Office Action asserts that Hernicz teaches "use of fiberoptic bundles for illuminating a sample" (Office Action, page 7), and the Office Action points to Hernicz's Summary of the Invention and Figure 3 for support of this assertion. The portion of Hernicz's Summary of the Invention that mentions fiberoptic bundles states, "Reference and sample fiberoptic bundles, photoelectric detectors lens assemblies are provided to measure diffuse light reflected from the sample." (Hernicz, column 2, lines 34-37). Thus, Hernicz's Summary of the Invention refers solely to use of fiberoptic bundles for measuring light reflected from the sample, and does not teach or suggest use of fiberoptic bundles for transmitting light from a light source to the surface of a test strip.

Figure 3 of Hernicz shows lamp **38**. Lamp **38** in Figure 3 is not shown to be optically coupled with a fiberoptic bundle such that the fiberoptic bundle

would transmit light from lamp **38** to the test strip surface. Moreover, the text of Hernicz that describes the fiberoptic bundles of Figure 3 states, "Both the sample fiber-optic bundle **54** and reference fiber-optic bundle **56** transfer diffusely reflected light from sample **36** and readhead **20**, respectively, through a filter **58** to a pair of detectors **60** and **62**, as well known in the art." (Hernicz, column 5, lines 24-28). Thus, Figure 3 shows that the fiberoptic bundles are coupled to detectors, so that the fiberoptic bundles transmit light reflected from the test strip to the detector. However, Figure 3 and accompanying text do not teach or suggest the use of fiberoptic bundles for transmitting light from a light source to the surface of a test strip.

Therefore, the two portions of Hernicz, relied upon by the Office Action for the assertion that Hernicz teaches the use of fiberoptic bundles for illuminating a sample, teach only that the fiberoptic bundles are used for transmitting light reflected from the sample. Moreover, no other portion of Hernicz teaches or suggests use of fiberoptic bundles for transmitting light from a light source to the surface of a test strip. Accordingly, Hernicz does not teach or suggest transmitting light emitted from a light source through a fiberoptic bundle to the surface of a test strip, as recited in claims 29 and 30.

Since neither Connolly nor Augstein teach or suggest use of fiberoptic bundles, the cited references, when combined do not teach all of the elements of claims 29 and 30.

2. Modification of Hernicz would change Hernicz's principle of operation

Furthermore, modifying the device of Hernicz to transmit emitted light through a fiberoptic bundle to the surface of the test strip would change the principle of operation of Hernicz. The key principle of operation of Hernicz's reader head is the manner in which the reader head illuminates the test strip. (Hernicz, Abstract and column 4, lines 21-33). The reader head of Hernicz is configured such that the upper portion of the inner surface is hemispherically shaped and the lower portion is conically shaped. The purpose of this

configuration is to permit the light source to illuminate the sample surface with reduced height sensitivity. If the reader head of Hernicz were to be modified such that the emitted light was transmitted by a fiberoptic bundle to the surface of the sample, the method of illuminating the sample would be changed and the shape of the reader head would be rendered irrelevant; and, therefore, the benefits resultant from the shape of the reader head would be eliminated.

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If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention that is modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). Because the modification to Hernicz proposed by the Office Action would render the principle operation of the reader head of Hernicz useless, Hernicz cannot be combined with Connolly and Augstein to result in the methods of claim 29 or claim 30.

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In view of the above remarks and the amendments and remarks of record, reconsideration and allowance of the application are respectfully requested.

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